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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,282	12/19/2001	Mark W. Bleyer	3433-333	5918

7590 01/14/2004

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT PAPER NUMBER

1632

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER
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200401

**DATE MAILED:**

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner for Patents**

Applicant's election, dated 10/14/03, in response to the restriction of record is non-responsive. See the reasons set forth in the attached paper

Applicant's proposed election of a collagenous biomaterial, wherein the biomaterial comprises a submucosa is acknowledged in the response filed December 19, 2003. However, applicant's proposed election is not the same as the required species restriction of record, and thus, applicant in the response filed December 19, 2003 has not elected the species set forth in the species restriction. The issue is not that the examiner would not search the generic subject matter as claimed in claim 2, which clearly recites a collagenous biomaterial that comprises a tissue submucosa, nor would the examiner not search an even more generic subject matter as claimed in claim 19, which recites a generic radiopaque implantable biomaterial device which comprises a warm blooded vertebrate tissue submucosa. Furthermore, a search of one particular species of a tissue submucosa would not necessarily overlap with that of other species of tissue submucosa as listed in the claims. The same for numerous species of shape of the biomaterial devices or the material (the examiner notes no antecedent basis for the "material" as recited in claim 28). For applicant's convenience, the species restriction of record is reproduced here as follows:

Species Restriction to one of the following inventions is required under 35 U.S.C. 121:

The presently pending claims are generic to a plurality of disclosed patentably distinct species comprising:

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1/ A specific species of a combination of tissue submucosa as set forth in claims 3 and 4.

a/ For applicant's convenience, the species as listed in claim 3 are:

a bovine based tissue submucosa, a porcine based tissue submucosa, and a ovine based tissue submucosa;

b/ Should a specifically named species of tissue submucosa be elected, Applicant is further required to elect a particular organ based tissue submucosa as listed in claim 4.

The species are:

a tissue submucosa from alimentary tissue, a tissue submucosa from genital tissue, a tissue submucosa from urinary tissue, a tissue submucosa from respiratory tissue or organ, and a tissue submucosa from an integumentary submucosa.

2/ A specific species a radiopaque marker as recited in claims 6 and 9.

The species are:

Tantalum, barium sulphate, iodine, and bismuth oxychloride;

3/ A specific species of a device shape as set forth in claim 15 or claim 27.

For applicant's convenience, the species as listed in claim 15 or claim 27 are:

a coiled shape or a spring-like shape, a helical shape, a randomized shape, a branched shape, a sheet-like shape, a tubular shape, a spherical shape, and a fragmented shape.

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4/ A specific species of a material shape as set forth in claim 16 or claim 28.

For applicant's convenience, the species as listed in claim 16 or claim 28 are:

A fluidized shape, a comminuted shape, a liquefied shape, a suspended shape, a gel-like shape, an injectable shape, a powdered shape, a ground shape, a sheared shape, and a solid shape.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of item 1/a, 1/b, 2/, 3/, and 4/ as listed and cited above, even though this requirement is traversed. The combined features of the sources of the tissue submucosa such as a combination of alimentary/bovine, alimentary/porcine, or genital/bovine, for example, are distinct structurally and would not necessarily overlap with one another when a prior art search is conducted. Likewise, each species of a radiopaque marker is structurally distinct and a search of all listed ones and/or combination(s) of such together with other members and/or combination(s) of other Markush Groups would be unduly burdensome to the examiner.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35

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U.S.C. 103(a) of the other invention.

Because these species are structurally distinct, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and/or consider patentability of all of the claims as presently pending.

Applicant is advised that the response to this requirement to be complete must include an species election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Therefore, The response filed on December 19, 2003 is non-responsive (MPEP § 821.03).

Since the above-mentioned amendment appears to be a bona fide attempt to reply, Applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Please note that the examiner is expected to move to a new US PTO office building located in Alexandria on January 12, 2004. The examiner office phone number at the new building is **571-272-0731**.

Dave Nguyen  
Primary Examiner  
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A handwritten signature in black ink, appearing to read 'Dave T. Nguyen', with a long horizontal flourish extending to the right.

DAVE T. NGUYEN  
PRIMARY EXAMINER